September 29, 2006

SUBJECT: **PRODUCT CHEMISTRY REVIEW OF:** CDG Solution 3000

DP Barcode: [D331604] **Reg. No. or File Symbol:** [75757-E]
Manufacturing-Use [ ] **End-Use Product** [X]

TO: Karen Hicks, Team Leader
Product Science Branch
EPA Antimicrobials Division

FROM: CSC Systems & Solutions LLC

THRU: Wallace Powell
Product Science Branch
EPA Antimicrobials Division

APPLICANT: CDG Research Corporation
Bethlehem, PA

Product Formulation Active Ingredient(s):	**% by Wt.:**
Chlorine dioxide	0.3%

BACKGROUND:

CDG Research Corporation has submitted an application for registration of a new end-use product, CDG Solution 3000. The product is for use in treating water for human and animal consumption, including hospital and cruise ship water systems. The product may also be used to eliminate biological slime in food processing water and industrial processing water. The registrant provided a Confidential Statement of Formula (CSF) for the basic formulation. The product is produced by a non-integrated formulation system. The following registered products are the sources of the active ingredient, sodium chlorite: [redacted]

FINDINGS:

Description of the Production Process and Inputs, CDG Solution (MRID 468898-01); General Description of Chlorine Dioxide Aqueous Solution, "CDG Solution 3000" (MRID 468898-04); and Discussion of Formation of Impurities, CDG Solution 3000 (MRID 468964-01)

- All Group A product chemistry data requirements applicable to end-use products have been met, with the exception of 830.1750 (Certified Limits). Non-standard certified limits were proposed for the diluent without explanation. See the "Recommendations" section of this report for deficiencies. See also Table A of this report.

CDG Solution 3000, Verification of Initial Concentration and Storage Stability Study (MRID 468898-03)

- Group B product chemistry data requirements applicable to end-use products were not specifically addressed, with the exception of 830.6317 (Storage Stability). Information in the CSF and MSDS for the product generally satisfies Group B product chemistry data requirements for 830.6303 (Physical State), 830.6314 (Oxidation/Reduction; Chemical Incompatibility), 830.6315 (Flammability/Flame Extension), 830.6316 (Explodability), and 830.6319 (Miscibility).

- Information in the CSF and MSDS for the product provides some information to address Group B product chemistry data requirements for 830.7000 (pH) and 830.7300 (Density/Relative Density/Bulk Density). No information has been provided to address Group B product chemistry data requirements for 830.6320 (Corrosion Characteristics), 830.6321 (Dielectric Breakdown Voltage), and 830.7100 (Viscosity). See the "Recommendations" section of this report for deficiencies. See also Table B of this report.

Confidential Statement of Formula

- Information contained on the CSF is consistent with information provided in the data package.

Product Label

- The label ingredient statement, which lists the nominal concentration of the active ingredient, is consistent with information contained on the CSF.

RECOMMENDATIONS:

- To satisfy 830.1750 (Certified Limits) requirements, the registrant must explain the basis for the non-standard upper and lower certified limits proposed for the diluent. The registrant must also provide a signed certification statement.

- To satisfy 830.7000 (pH), 830.6320 (Corrosion Characteristics), 830.6321 (Dielectric Breakdown Voltage), 830.7100 (Viscosity), and 830.7300 (Density/Relative Density/Bulk Density) requirements, the registrant must provide the results of appropriate studies, conducted in compliance with GLP standards as set forth in 40 CFR Part 160. The registrant should submit product chemistry data in a single study for Group B – Physical/Chemical Properties (830.6302 through 830.7950), as specified in PR notice 86-5.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system [X]
- Are all TGAIs used registered? Yes [ ] No [ ]
- Integrated formulation system [ ]
- If "ME-TOO," specify EPA Reg. No. of existing product: _____

b. Clearance of inerts for non-food or food use:
The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [X] No [ ]

c. Physical state of product: *Liquid*

d. The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830 Series, Group B.
Yes [ ] No [X]

Note: Group B product chemistry data requirements were not specifically addressed.

e. The NCs and CLs are acceptable. Yes [ ] No [X]

Note: The basis for the proposed non-standard upper and lower certified limits for the diluent was not provided.

f. Active ingredient(s)	NC (%)	LCL (%)	UCL (%)
Chlorine dioxide	0.3%	0.27%	0.33%

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
  Yes [ ] No [ ] Not applicable [X]

- Have all impurities of ≥ 0.1% in the product been identified?
  Yes [ ] No [ ] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient(s) statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes [X] No [ ]

b. The formula contains one of the following:

- 10% or more of a petroleum distillate: Yes [ ] No [X]
- 1.0% or more of methyl alcohol: Yes [ ] No [X]
- sodium nitrite at any level: Yes [ ] No [X]
- a toxic List 1 inert at any level: Yes [ ] No [X]
- arsenic in any form: Yes [ ] No [X]

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes [ ] No [ ] Not applicable [X]

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.
Yes [ ] No [ ] Not applicable [X]

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.
Yes [X] No [ ]

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).
Yes [X] No [ ]

Note: The label identifies an expiration date.

Table A:
Product Chemistry (830 Series, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity[1]	A	CSF and MSDS
830.1600 Description of Materials	A	468898-01

Data Requirements	Acceptance of Information	MRID No.
830.1620 Production Process[2]	A	468898-01; 468898-04
830.1650 Formulation Process[3]	NA	
830.1670 Formation of Impurities[4]	A	468898-04; 468964-01
830.1700 Preliminary Analysis[5]	Not required. The product does not consist solely of a TGAI and is not produced by an integrated system.	
830.1750 Certified Limits[6]	G – The basis for the proposed non-standard upper and lower certified limits for the diluent was not provided. A signed certification statement was not provided.	CSF
830.1800 Analytical Method[7]	A – The registrant provided a reference for a titration method.	468898-01
830.1900 Submittal of Samples	[Samples are to be provided on a case-by-case for end-use products.]	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

[1]See Confidential Appendix A for additional information
[2]For MP/EP products produced by an integrated formulation system.
[3]For products from a TGAI or MP.
[4]May be waived unless actual/possible impurities are of toxicological concern.
[5]Five batch analysis required for products produced by an integrated formulation system.
[6]If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.
[7]Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	NA	Not required for end-use products.	
830.6303 Physical State	A	The product is a liquid.	MSDS
830.6304 Odor	NA	Not required for end-use products.	
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NA	Not required for end-use products.	
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	Contact with the following should be avoided: metals, reducing agents, strong oxidizing agents, sulfur compounds or sulfur-containing compounds, carbon	MSDS

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
		monoxide, excessive heat, mercury, organic materials, and phosphorus.	
830.6315 Flammability/Flame Extension	A	The product is an aqueous solution. Flash point is not applicable.	CSF and MSDS
830.6316 Explodability	A	The product is not explosive.	MSDS
830.6317 Storage Stability	A	Storage stability studies were conducted at 10°C, 25°C, and 40°C. Based on the reduction of chlorine dioxide concentrations observed, the label includes a shelf-life limit of 90 days.	468898-03
830.6319 Miscibility[1]	A	The product is an aqueous solution.	CSF
830.6320 Corrosion Characteristics	U		
830.6321 Dielectric Breakdown Voltage	U		
830.7000 pH[2]	G	The product has a neutral pH.	468898-04
830.7050 UV/Visible Absorption	NA	Not required for end-use products.	
830.7100 Viscosity	U		
830.7200 Melting Point/Melting Range	NA	Not required for end-use products.	
830.7220 Boiling Point/Boiling Range	NA	Not required for end-use products.	
830.7300 Density/Relative Density/Bulk Density	G	The specific gravity of the product is 1.0 at 0°C.	MSDS
830.7370 Dissociation Constants in Water	NA	Not required for end-use products.	
830.7550/830.7560/830.7570 Partition Coefficient	NA	Not required for end-use products.	
830.7840/830.7860 Water Solubility	NA	Not required for end-use products.	
830.7950 Vapor Pressure	NA	Not required for end-use products.	

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

[1]If product is an emulsifiable liquid
[2]If product is dispersible with water